IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC
PELVIC REPAIR SYSTEM,
PRODUCTS LIABILITY LITIGATION MDL NO. 2327
- -

THIS DOCUMENT RELATES TO ALL CASES

FIRST AMENDED NOTICE TO TAKE ORAL DEPOSITION
OF DEFENDANT ETHICON LLC THROUGH DESIGNATED WITNESS(ES)

TO: Defendant ETHICON, LLC and its Attorneys of Record.

Please take notice that pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure, Plaintiffs, by and through their counsel, will take the videotaped deposition of a designated witness or witnesses of Defendant Ethicon, LLC to begin on May 28, 2013, at 9:00 a.m., at the offices of Riker Danzig at One Speedwell Avenue in Morristown, New Jersey. The witness(es) shall be prepared to testify concerning the subject matters identified in Exhibit "A", attached hereto. The witness(es) shall produce documents identified in Exhibit "B", attached hereto, prior to the deposition. The deposition will be taken before a person authorized by law to administer oaths, pursuant to Rule 28 of the Federal Rules of Civil Procedure, and will continue day-to-day until the examination is completed.

DEFINITIONS

All definitions and rules or instructions set forth in Fed. Rule Civ. P. 30(b)(6) shall apply to all requests for information herein. To the extent a term commonly in use in the medical device industry is not defined herein, it shall be understood to be consistent with the meaning commonly ascribed to that term in the medical device industry.

1. "Concerning" means referring to, describing, evidencing, or constituting. See LR Civ. P 26.2(c)(7).

2. “Defendant”, “Ethicon, LLC”, “you” or “your” refers to, without limitation, Ethicon, LLC and all business entities with which it is or has been affiliated, together with any predecessor, successor, parent, or subsidiary entity as well as any officer, director, employee, attorney, agent, or representative of any such other business entity previously described herein.

3. “Document” is synonymous in meaning and equal in scope to the usage of this term in Rule 34(a) of the Federal Rules of Civil Procedure and expressly includes writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations stored in any medium from which information can be obtained either directly or, if necessary, after translation by you into a reasonably usable form. A draft or non-identical copy is a separate document. *See* LR Civ. P. 26.2(c)(2); *see also* FR Civ. P 34(a).

4. “Mesh Product” means any product that you developed, designed, distributed, licensed, manufactured, marketed or sold for the treatment of Pelvic Organ Prolapse (POP) or Stress Urinary Incontinence (SUI).

5. “Relevant Time Period” means the time period from when you first developed, designed, distributed, licensed, manufactured, marketed or sold pelvic mesh products to the present.

PLAINTIFFS’ CO-LEAD COUNSEL

By: ____/s/Thomas P. Cartmell_______________
THOMAS P. CARTMELL
Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
816-701-1102
Fax 816-531-2372
tcartmell@wcllp.com

D. RENEE BAGGETT
Aylstock, Witkin, Kreis and Overholtz, PLC
17 E. Main Street, Suite 200
Pensacola, FL 32563
850-202-1010
850-916-7449
Rbaggett@awkolaw.com
Plaintiffs' Co-Lead Counsel

EXHIBIT "A"

DEPOSITION SUBJECT MATTER

Pursuant to Rule 30(b)(6), the deponent(s) must have knowledge and shall be able to testify concerning the following subject matters:

I. ETHICON LLC COMPANY STRUCTURE AND ORGANIZATION

1. Ethicon, LLC's internal company structure and organization, and more specifically:

a. The internal organizational structure of Ethicon, LLC's individual departments, groups, divisions, committees and/or task forces;

b. The organizational structure within each of Ethicon LLC's departments, groups, divisions, and/or committees, including the identity of the individuals who performed work related to your pelvic mesh products;

c. All persons, departments, and/or committees involved in the research, development, production, regulatory compliance, testing, packaging, distribution, sanitization, manufacturing and quality control of Ethicon LLC's pelvic mesh products;

d. The functions, duties and responsibilities of each department, group, division, and/or committee related to the manufacturing of your pelvic mesh products; and

e. The members of Ethicon, LLC.

2. The nature, location, storage and organization of all documents and electronically stored information related to any activities of Ethicon LLC, including any activities of its boards of directors and/or board of director committees and subcommittees, meeting minutes, reports, handouts and investigational documents from the date Ethicon, LLC first started manufacturing its pelvic mesh products (including but not limited to any of their component parts or materials used in the manufacturing process) until the present.

3. The contractual relationship and the contracts with any and all vendors, suppliers or other third parties related to the supply of materials or component parts for the manufacture of the pelvic mesh products or in any way related to the manufacture of the pelvic mesh products.

4. The structure of any working or functional department or group, committee, and/or task force including the identity of those individuals responsible for tracking, recording, reporting, handling, or following up on complaints, adverse events or other non-conformance issues or problems related to the manufacture of the pelvic mesh products.

5. Ethicon LLC's contract(s) and relationships with Medical Device and Diagnostics Global Services, LLC, including all aspects of the agreement and each parties' duties and responsibilities pursuant to the agreement.

6. The company organization and structure of Ethicon LLC relating to the approval, management, administration, operation and compliance with any and all U.S. medical device regulations or standards applicable to your pelvic mesh products from the date Ethicon LLC first started developing pelvic mesh products until the present.

7. The company organization and structure of Ethicon LLC relating to the approval, management, administration, operation and compliance with any and all foreign medical device regulations or standards applicable to your pelvic mesh products from the date Ethicon LLC first started developing pelvic mesh products until the present.

II. MANUFACTURING AND DISTRIBUTION PRACTICES

1. The following manufacturing topics and the identity of all persons within Ethicon, LLC and all committees, groups, departments, and/or boards and the like (including their names, responsibilities, dates of operation and the identity of their members), who/which were

responsible at any and all time periods for the following from the date Ethicon, LLC first started manufacturing and distributing its pelvic mesh products until the present:

a. All raw materials, including additives, that are contained in the polypropylene mesh used in your pelvic mesh products, including the suppliers of all such products;

b. The existence and handling of manufacturing related complaints and non-conformance reports;

c. The method of supply and the identity of the suppliers of any and all materials or component parts of your pelvic mesh products;

d. Sterilization and sanitization of the product, plant and equipment used in the manufacture of the pelvic mesh products, including those responsible for developing policies and procedures regarding sterilization and sanitization and those responsible for ensuring compliance with those policies and procedures;

e. The maintenance of records regarding the sterilization and sanitization of the product, plant and equipment used in the manufacture of the pelvic mesh products, including maintaining and updating policies and procedures regarding sterilization and sanitization;

f. The specifications for all materials and/or component parts that make up you pelvic mesh products;

g. Inspecting, measuring, testing, and otherwise ensuring compliance with specifications for finished products;

h. Inspecting, measuring, testing, and otherwise ensuring compliance with specifications for product components;

i. Inspecting, measuring, testing, and otherwise ensuring compliance with specifications for product raw materials;

j. End-to-end production process for pelvic mesh products, including the purchasing, testing and chemical composition of raw material, the extrusion of continuous filament, winding, weaving, knitting, scouring, and/or annealing;

k. Inspecting finished mesh products for surface effects and/or variations in the finished products;

l. Measuring process variables, including temperature effects at the extrusion die, water content of the polymer, the finish of the tool and/or residual process materials that have not been completely removed through scouring;

m. Measuring polypropylene variables, including tacticity, presence of extrusion processing aids, monomers, dimers and/or residual catalyst;

n. Implementing and maintaining any manufacturing and distribution process tracking technologies employed by Ethicon LLC, including but not limited to technologies such as RFID and barcodes and the means of collection, retention and integration of these data through the product lifecycle;

o. Installing, inspecting, maintaining, and operating equipment used to produce pelvic mesh products, including, but not limited to laser cutting equipment and mechanical cutting equipment used in the production of pelvic mesh;

p. The substantive preparation, printing, and placement of package inserts, product packaging, IFUs and other labeling for your pelvic mesh products (both U.S. and foreign), including the specific dates of use for each such items and any changes thereto;

q. The substantive preparation and approval of any manufacturing process changes regarding your pelvic mesh products, including the specific dates and reasons for each change;

r. Any investigation, evaluation and determination as to whether there is an association between manufacturing defects/problems/errors related to your pelvic mesh products and any adverse event experienced by a patient who was provided your pelvic mesh products;

s. Any investigation, evaluation and determination as to whether there is an association or causal connection between your pelvic mesh materials, component parts or products and any adverse event or injuries;

t. Any documents which pertain to or discuss personal injury litigation concerning your pelvic mesh product, including but not limited to documentation of litigation holds;

u. The maintenance of Ethicon LLC's finances, budgets and expenditures related to its pelvic mesh products from the date first started developing and manufacturing its pelvic mesh products until the present;

v. The interaction and communication internally or with any outside contractors, vendors or consultants regarding the manufacturing, engineering, distribution, regulatory compliance, or the safety of your pelvic mesh products for use by humans, from the date Ethicon, LLC first started developing and manufacturing pelvic mesh products until the present;

w. The interaction and communication internally or with any outside vendors regarding the safety of the use of the raw materials used in the manufacturing of your pelvic mesh products, from the date Ethicon, LLC first started developing, packaging and/or manufacturing pelvic mesh products until the present;

x. Any internal communications or external communication with vendors, suppliers, contractors or consultants related to whether polypropylene is safe for use in your pelvic mesh products;

y. The Corrective and Preventative Action Plan (“CAPA”) relating to failure to properly maintain documents necessary for regulatory or litigation purposes;

z. Any material safety data sheets for polypropylene or product safety data sheets for polypropylene in your possession from the date you first started manufacturing your pelvic mesh products;

aa. Any material safety data sheets or product safety sheets for the raw materials or component parts of your pelvic mesh products from the date you first started manufacturing your pelvic mesh products;

bb. The Corrective and Preventative Action Plan (“CAPA”) relating to failure of Prolene Mesh not being packaged (folded) as specified in the Process Specification for Packaging of Mesh Product;

cc. The Corrective and Preventative Action Plan (“CAPA”) relating to Gynemesh non-absorbable Prolene Soft mesh not being properly sealed as well as evaluating units for packaging integrity;

dd. The Corrective and Preventative Action Plan (“CAPA”) related to the increase in complaints with the TVT-Secur in Australia reported by Dr. Aran Maree.

ee. The Corrective and Preventative Action Plan (“CAPA”) related to defective inserter springs in the TVT-Secur.

ff. Documentation of Investigations of causes of manufacturing nonconformities and corrective and preventative actions (“CAPA”);

gg. The auditing of the conduct of the company and its officers and employees in connection with the manufacture, distribution, testing and quality of pelvic mesh products from the date Ethicon, LLC first started developing pelvic mesh products until the present;

hh. Ethicon LLC's quality manual, quality policy, written procedures for management review, quality audits and quality plan and management review of the same;

ii. Manufacturing standards for measuring space between pores of pelvic mesh products as well as evaluation and testing of the space between the pores;

jj. Rejected Product that did not meet product specifications as well as the destruction or disposal of such product including records of the product;

kk. The suppliers of the polypropylene mesh, including any contracts with any third parties about or relating to the supply of polypropylene mesh; and

ll. The existence of and terms of all hold harmless agreements or indemnification agreements between Ethicon LLC and its vendors, suppliers, consultants, distributors or other manufacturers of pelvic mesh products.

2. The processes and procedures used by Ethicon, LLC in connection with processing of non-conformance reports, including the identification of policy manuals, SOPs, and safety manuals.

3. The process and procedures for storing, testing and/or analyzing pelvic mesh products that have been returned to Ethicon, LLC due to complaints of malfunction or complications and the location of any and all such storage facilities.

III. OUTSIDE CONTRACTORS/CONSULTANTS

1. All persons or entities that Ethicon, LLC (including the name, employer or the corporate entity the person is associated with, the time period in which the relationship existed, the title, role, function of the individual or entity, and a general description of the nature of the consultation or discussion) consulted with, paid or retained concerning your pelvic mesh

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products from the date Ethicon, LLC first started developing pelvic mesh products until the present. Areas of inquiry related to the identity of these consultants will include but will not be limited to the following:

a. Ensuring and/or evaluating compliance with laws and regulations regarding product manufacturing;

b. Ensuring and or evaluating compliance with quality manufacturing procedures and policies, included but not limited to auditing of procedures such as ISO 9000 and any similar procedures;

c. Any consultants involved in responding to any perceived deficiencies to Ethicon LLC's processes or manufacturing, including Corrective and Preventative Actions, (CAPA's) Product Quality Issues (PQI's), or non-conformance issues or problems;

d. Any consultants involved with testing, maintenance, repair, setup and operation of plant equipment;

e. Any scientific, manufacturing, and engineering consultants;

f. Any product testing consultants;

g. Any machine testing consultants;

h. Any consultants or contractors involved with the supply of mesh, the type of mesh to be used in the pelvic floor mesh products, or the safety of the mesh to be used in the pelvic floor mesh products.

2. Ethicon LLC's third party consultants or entities retained for Manufacturing, Engineering, Product Testing, Auditing, and the nature of the work done by those consultants and the time periods during which they were retained from the date Ethicon LLC first started developing pelvic mesh products until the present.

VI. REGULATORY COMMUNICATIONS

1. All interactions between Ethicon LLC and the FDA or other regulatory bodies in the United States concerning Ethicon LLC's manufacturing or distribution of pelvic mesh products or component parts making up such pelvic mesh products, including the location, storage and organization of any and all documents that relate to or reflect the same.

2. Communications between Ethicon LLC and the FDA or other federal government entity or agency regarding the manufacturing of pelvic mesh products.

EXHIBIT "B"

DOCUMENT REQUESTS

Please produce:

1. All documents relied upon by the deponent in preparing for this deposition.

2. All documents reflecting correspondence between the FDA and Ethicon LLC regarding pelvic mesh products or facilities and procedures involved in the manufacture of pelvic mesh products.

3. All current and former product specifications for pelvic mesh products including draft copies.

4. Ethicon LLC's quality manual, quality policy, written procedures for management review, quality audits and quality plan as well as minutes and notes management review meetings regarding these documents.

5. Any documents indicating or discussing deviation from product specifications, including but not limited to, fraying, bunching, curling, degradation, fading, crumbling, folding, toxicity or sizing of mesh.

6. Records of product that was rejected and destroyed or otherwise disposed for not meeting product specifications.

7. All agreements between Ethicon LLC and third parties or consultants related to the supply of mesh for use in pelvic floor products.

8. All documents related to whether the use of polypropylene mesh is safe for use in humans.

9. Any material safety data sheets for polypropylene or product safety data sheets for polypropylene in your possession from the date you first started manufacturing your pelvic mesh products.

10. Any material safety data sheets or product safety sheets for the raw materials or component parts of your pelvic mesh products from the date you first started manufacturing your pelvic mesh products